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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/054,487

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Brian Lauman

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BAXTER HEALTHCARE CORPORATION

RENAL DIVISION

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EXAMINER

FRANK, RODNEY T

ART UNIT

PAPER NUMBER

2856

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/054,487	Applicant(s) LAUMAN ET AL.	
	Examiner Rodney T. Frank	Art Unit 2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 23-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
6) <input type="checkbox"/> Other: _____. |
|--|--|

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-5, 7-11, 14-20, 23, 28, 30-35, 37-41, 43, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Rogers (U.S. Patent Number 6,210,368). Rogers discloses reservoir volume in a drug delivery device is sensed by providing a capacitor, the capacitance of which varies with bellows position or, alternatively, with the amount of propellant liquid absorbed in a dielectric material. In one embodiment, a capacitance is provided between a surface of the bellows, which acts as a first capacitor plate, and a conductive surface disposed proximate the bellows, which acts as a second capacitor plate. As the bellows moves from its extended full position to its collapsed empty position, the area of overlap, and therefore the capacitance between the first and second plates varies from a maximum value to a minimum value. In another embodiment, a variable capacitor is provided with an absorbent material. The absorbent material

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absorbs the liquid phase of the propellant in the pump housing and acts as a dielectric between two stationary conductive plates provided in the housing. The amount of liquid propellant absorbed in the absorbent material varies with the reservoir volume. When the reservoir is in its full, expanded position, more liquid propellant is absorbed in the absorbent material. When the reservoir is in its compressed empty position, more of the propellant exists as vapor within the pump housing and therefore less liquid propellant is absorbed in the absorbent material. The dielectric properties of the capacitor are therefore higher and the capacitance is therefore maximized when the reservoir is in its full, extended position. Conversely, the dielectric properties are lower and the capacitance minimized when the reservoir is in its compact, empty position (Please see the abstract).

3. In reference to claim 1, Rogers discloses and shows in the figures a device for providing a medical fluid to a patient comprising a plurality of capacitor plates positioned in a fixed relation to one another (see figure 1, items 26 and 34); a fluid receptacle positioned between the capacitor plates (bellows 22), a circuit electrically connected to the capacitor plates having an output indicative of a volume of the fluid in the receptacle (see wire 38 in figure one and column 4 lines 17-24) a member (not shown) for providing at least a portion of the volume of the fluid to or from a patient.

In reference to claim 2, the pump chamber is shown in figure 1 and is also specifically claimed in claim 11 where a bulkhead (20) is disclosed for sealing the pump housing and defining an inner chamber therewith.

In reference to claim 3, the capacitor plates are shown to have a shape similar to that of the chamber (see specifically figure 1 item 34).

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In reference to claims 4 and 5, the bellows are at least one flexible membrane wall moveable to pump medical fluid, and first and second membrane walls moveable to change a volume of the receptacle.

In reference to claims 7 and 8, the plate 26 formed on the wall of the bellows has a non-planar shape and is also the same shape as the bellows either full or empty.

In reference to claims 9 and 10, the circuit measures the capacitance in methods well known in the art, according the disclosure of Rogers, and therefore would meet the limitations of these claims. For support in the disclosure, please see column 4 lines 17-24).

In reference to claim 11, the capacitor plates are shown to be substantially parallel.

In reference to claim 14, the general spirit of the invention is a pump for medical fluid to or from a patient, the fluid receptacle capable of being fluidly connected to a patient, first and second capacitor plates having a variable dielectric between the plates that is dependent on an amount of a fluid in the fluid receptacle, and a circuit connected to the capacitor plates that creates a signal related to the variable dielectric.

In reference to claims 15-17, the method of measure disclosed in Rogers would meet these claim limitations.

In reference to claims 18-20, these limitations were discussed at length above with regard to the disclosure of Rogers.

In reference to claim 23, column 3 lines 29-31 disclose the use of a propellant to maintain pressure on the bellows.

In reference to claim 28, it is disclosed conventional circuitry can be used to determine capacitance, as discussed above. Since a processor would be a part of conventional capacitive measurement circuitry, then this limitation is disclosed.

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In reference to claim 30, the shape of the plates was already covered in view of the discussion of claim 8 above.

In reference to claims 31-35, 37-41, 43, and 44, these claims were discussed at great details in reference to the previous claims discussed and these claims are therefore deemed to be disclosed in view of the Rogers reference.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6, 12, 13, 24-27, 29, 36, and 42-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers (U.S. Patent Number 6,210,368).

6. Rogers, as discussed above, discloses the basic limitations of the present invention.

However, with regards to claims, 6, 12, 13, 45, 46, and 47-50 though the use of a dialysis fluid is not specifically disclosed, dialysis fluid is a medical fluid and therefore the use of a dialysis fluid, and the various design parameters which are associated with a dialysis system, would be obvious to one of ordinary skill in the art at the time of the invention.

7. With regard to claims 24-27, 29, 36, and 42, though these specific details of the present invention are not specifically disclosed in the Rogers reference, they are deemed to be merely a design choice of the applicant that does not change the operation of the device nor deviate from the spirit of the Roger reference, nor provide and disclosed advantage or unexpected result and would therefore also be obvious to one of ordinary skill in the art at the time of the invention.

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With regard to claims 51-73, the various methods disclosed are not specifically disclosed in the Rogers reference. However, since the various devices are either specifically disclosed or deemed obvious in view of Rogers, then the various methods of using those various devices would also be obvious to one of ordinary skill in the art at the time of the invention in view of the teachings of Rogers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney T. Frank whose telephone number is (571) 272-2193. The examiner can normally be reached on M-F 9am -5:30p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTF
September 5, 2004

HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800

